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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,293	08/24/2001	Emad S. Alnemri	480140.465	2539

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,293	ALNEMRI, EMAD S.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-96* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, 87, drawn to nucleic acid molecules encoding peptide or polypeptide fragments of SEQ ID NO:1, classified in class 536, subclass 23.1.

II. Claims 28-51, 88, drawn to peptide or polypeptide fragments of SEQ ID NO:1, classified in class 530, subclass 300.

III. Claims 52-54, drawn to a method for inducing apoptosis in a cell, or tumor cell, using a peptide or polypeptide fragment of SEQ ID NO:1, classified in class 514, subclass 2.

IV. Claims 52-54, drawn to a method for inducing apoptosis in a cell, or tumor cell, using a nucleic acid molecule encoding a peptide or polypeptide fragment of SEQ ID NO:1, classified in class 514, subclass 2.

V. Claims 52-54, drawn to a method for inducing apoptosis in a cell, or tumor cell, using a peptide or polypeptide fragment of SEQ ID NO:1, and a nucleic acid molecule encoding a peptide or polypeptide fragment of SEQ ID NO:1, classified in class 514, subclass 2.

VI. Claims 55-56, drawn to a method for inducing apoptosis in a tumor cell that overexpresses an inhibitor of a caspase, using a peptide or polypeptide fragment of SEQ ID NO:1, classified in class 514, subclass 2.

VII. Claims 55-56, drawn to a method for inducing apoptosis in a tumor cell that overexpresses an inhibitor of a caspase, using a nucleic acid molecule encoding a peptide or polypeptide fragment of SEQ ID NO:1, classified in class 514, subclass 44.

VIII. Claims 52-54, drawn to a method for inducing apoptosis in a tumor cell that overexpresses an inhibitor of a caspase, using a peptide or polypeptide fragment of SEQ ID NO:1, and a nucleic acid molecule encoding a peptide or polypeptide fragment of SEQ ID NO:1, classified in class 514, subclasses 2 and 44.

IX. Claim 57, drawn to a method for identifying an inhibitor of a caspase-mediated apoptosis, comprising contacting a cell transformed with a vector expressing a peptide or polypeptide fragment of SEQ ID NO:1, and detecting cell viability, classified in class 435, subclass 252.3.

X. Claim 57, drawn to a method for identifying an enhancer of a caspase-mediated apoptosis, comprising contacting a cell transformed with a vector expressing a peptide or polypeptide fragment of SEQ ID NO:1, and detecting cell viability, classified in class 435, subclass 252.3.

XI. Claims 58-59, drawn to a method for identifying an inhibitor of a caspase-mediated apoptosis, comprising contacting a cell transformed with a vector expressing a peptide or polypeptide fragment of SEQ ID NO:1, and detecting a decrease of large and small caspase subunits, classified in class 435, subclass 4.

XII. Claims 58-59, drawn to a method for identifying an enhancer of a caspase-mediated apoptosis, comprising contacting a cell transformed with a vector expressing a

peptide or polypeptide fragment of SEQ ID NO:1, and detecting an increase of large and small caspase subunits, classified in class 435, subclass 4.

XIII. Claims 60-61, 63, drawn to a method for identifying a compound that inhibits caspase activity, thereby inhibiting apoptosis, comprising measuring the specific apoptotic activity, classified in class 435, subclass 4.

XIV. Claims 60-61, 64, drawn to a method for identifying a compound that promotes the activity of a cell survival polypeptide, thereby inhibiting apoptosis, comprising measuring the specific apoptotic activity, classified in class 435, subclass 4.

XV. Claims 60-61, 65, drawn to a method for identifying a compound that exhibits cell death inhibitory activity, thereby inhibiting apoptosis, comprising measuring the specific apoptotic activity, classified in class 435, subclass4 .

XVI. Claims 60-61, 62-63, drawn to a method for identifying a compound that inhibits caspase activity, thereby inhibiting apoptosis, comprising measuring the specific apoptotic activity of testing cells, and caspase activity in a lysate of testing cells, classified in class 435, subclass 4.

XVII. Claims 60-61, 64, drawn to a method for identifying a compound that promotes the activity of a cell survival polypeptide, thereby inhibiting apoptosis, comprising measuring the specific apoptotic activity of testing cells, and caspase activity in a lysate of testing cells, classified in class 435, subclass 4.

XVIII. Claims 60-61, 65, drawn to a method for identifying a compound that exhibits cell death inhibitory activity, thereby inhibiting apoptosis, comprising measuring the specific

apoptotic activity of testing cells, and caspase activity in a lysate of testing cells, classified in class 435, subclass 4.

XIX. Claims 66-72, drawn to a method for identifying a compound that inhibits Smac binding to a Smac-binding protein, comprising detecting displacement for inhibition of binding of said Smac binding to a Smac-binding protein, classified in class 435, subclass 4.

XX. Claims 73-75, drawn to a method for identifying a compound that inhibits Smac binding to a Smac-binding protein, comprising detecting the presence of large and small caspase subunits, classified in class 435, subclass 4.

XXI. Claims 73, 75-77, drawn to a method for identifying a compound that inhibits Smac binding to a Smac-binding protein, comprising detecting the presence of a substrate cleavage product produced by a caspase cleavage of a substrate, classified in class 435, subclass 4.

XXII. Claims 78-86, 89-90, drawn to an antibody that specifically binds to a peptide or polypeptide fragment of SEQ ID NO:1, classified in class 530, subclass 387.1.

XXIII. Claims 91-93, drawn to a polynucleotide encoding a cytosolic isoform of Smac, classified in class 536, subclass 23.1.

XXIV. Claims 94-96, drawn to a cytosolic polypeptide isoform of Smac, classified in class 530, subclass 350.

In addition, upon the election of any of groups I-XII and XXII, further election of the following patentably distinct species of the claimed invention is required:

1) Residues 56-139 of SEQ ID NO:1, 2) residues 56-239 of SEQ ID NO:1, 3) the sequence of at least Ala-Val, and 4) SEQ ID NO:13.

Upon the election of any of groups I, II, and XIX, XXII, further election of the following patentably distinct species of the claimed invention is required:

BIR1, BIR2 or BIR3 or any one combination of BIR1, BIR2 and BIR3.

Upon the election of any of groups VI-VIII, XX-XXI, further election of the following patentably distinct species of the claimed invention is required:

Caspase-3, caspase-7 or caspase-9.

The inventions are distinct, each from each other because of the following reasons:

Inventions (I-II, XXII-XXIV) and (III-XXI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The products of groups I-II, XXII-XXIV are patentably distinct, because they are drawn to entirely different biochemicals , having different structures

The methods of groups III-XXI are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species fragments of SEQ ID NO:1 are distinct because they are structurally distinct.

The species BIR1, BIR2 or BIR3 are distinct because they are structurally distinct.

The species caspases are distinct because they are structurally distinct.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

November 16, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600